

K951581

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ADAC LABORATORIES  
540 ALDER DRIVE  
MILPITAS, CA 95035

### III. SMDA 510(k) SUMMARY

#### A. OVERVIEW

This 510(k) application requests premarket clearance for the ADAC Pinnacle<sup>3</sup> APEX™ device (APEX), a radiation treatment planning software manufactured by ADAC Laboratories of Milpitas, California. This software device is intended to assist in formulating radiation treatment plans for modalities including stereotactic radiosurgery, external photon beam, external electron beam, and brachytherapy radiation treatment of benign or malignant disease processes.

The APEX software system is an extension and enhancement of the currently marketed ADAC Pinnacle<sup>3</sup> software (K926008), which also is also a radiation treatment software with a similar array of imaging, display, and dose computation capabilities. However, its approved intended use is only for stereotactic radiosurgery. The APEX offers the identical imaging, display and stereotactic radiosurgery capabilities, but its intended uses have been expanded to also include brachytherapy, external electron beam, and external photon beam treatment planning capabilities.

The predicate devices for the additional intended uses are the ADAC XL CAD Plan (K894706) and Precision Therapy Inc. Render-Plan 3-D (K894722). Each of the intended uses are discussed below.

#### B. STEREOTACTIC RADIOSURGERY

The Pinnacle<sup>3</sup> is the predicate device for the APEX for the stereotactic radiosurgery intended use. The two devices have identical stereotactic radiosurgery capabilities and identical visualization functions. The addition of the other planning functions has not affected the safety and efficacy of the APEX for this use.

### **C. EXTERNAL PHOTON BEAM**

The APEX software also contains the capability to formulate treatment plans for external photon beam therapy, as do both the CAD Plan and the Render-Plan 3-D. However, the APEX uses a Superposition Convolution Model method to compute photon dose, replacing the table lookup methods used by these predicates. This Convolution method uses measured beam data to model iteratively the computed beam profile. To compute dose, the associated kernel is superimposed on the dose grid and convolved with the primary fluence distribution. The kernel is then scaled in three dimensions according to patient densities (taken directly from patient images) to account for patient heterogeneities, beam modifiers, etc., to arrive at absolute dose per unit fluence.

The predicate devices use two dimensional algorithms to calculate photon dose, whereby measured beam data is used with a series of correction factors to account for patient heterogeneities, beam modifiers, etc., for a manually specified patient contour. This algorithm calculates relative dose per unit fluence.

The other aspects of photon therapy planning in the APEX system -- entry of measured physics data, beam modifiers, the energies and treatment machines supported -- are equivalent to the predicates.

Task Group #23 of the American Association of Physicists in Medicine has produced bench testing guidelines for photon beam planning software systems. Testing of the photon beam performance of the APEX that conforms to these guidelines has been conducted. The results verify the performance of the Convolution method for computing photon dose, and is provided in the 510(k).

#### **D. EXTERNAL ELECTRON BEAM**

For external electron beam planning, the predicates for the APEX are again both the CAD Plan and the Render-Plan 3-D devices. All three use the same physics data entry to create the dose lookup tables, and use pencil beam algorithms based on those created by Hogstrom et al to calculate dose. The APEX is able to perform both 2-D and 3-D electron dose calculation. All three systems support 2 - 20 MeV of electron energy, and use the same dose analysis tools (dose volume histogram and beam weight optimization.)

#### **E. BRACHYTHERAPY**

For brachytherapy planning, the APEX system is substantially equivalent to the ADAC XL CAD Plan System in terms of dose calculation methods. Both systems provide intracavitary and interstitial planning for the same types of radiation sources, including seeds, tubes and ribbons. The same Sievert Integral-equivalent table lookup method is used to compute dosage. Both the APEX and CAD Plan provide planar display of isodose distribution. Parallel testing was conducted to demonstrate the equivalence of brachytherapy planning in these two systems, and is provided in the 510(k).

The APEX also contains two additional features: calculation for High Dose Rate (HDR) therapy and volumetric dose display. The CAD Plan is capable of performing HDR calculation but this claim was not included in the prior 510(k) submission. Instead, the Render-Plan 3-D radiation treatment planning software (Precision Therapy Inc., K894722) which includes high dose rate as a claim in its labeling, serves as the predicate for this feature and for volumetric dose display. The HDR function for the APEX and Render-Plan contains the same dose algorithm capable of calculating at the higher dose rate.

## **F. PERFORMANCE TESTING**

The performance testing, including bench testing, parallel testing, and beta site testing will be thoroughly performed and verified prior to release of the product. The protocols and results of these tests are provided in Appendix D of the 510(k).

## **G. SOFTWARE DEVELOPMENT AND VERIFICATION**

Software development, validation and verification of the APEX system has been conducted according to the policies and procedures discussed in the 510(k), which includes engineering diagrams, fault tree analyses, the Verification and Validation documentation, and all pertinent reference articles. These documents can be found in Appendix E.

## **H. LABELING**

All draft labeling associated with the APEX has been presented in the 510(k) document, including the draft *User's Guide*, the *Physics Guide*, an outline of the training program, and promotional literature. The labeling available for the predicate devices -- the Pinnacle<sup>3</sup>, the CAD Plan, and the Render-Plan -- are also provided.